

Notice of Allowability

Application No.

10/099,880

Examiner

Olga N. Chernyshev

Applicant(s)

WEKSLER ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/17/4.
2. ☒ The allowed claim(s) is/are 1,5,6,8,9 and 16-18.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

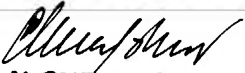
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |


OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER

EXAMINER'S AMENDMENT

1. Claims 1 and 16 have been amended and claims 7, 10, 14-15 and 27 have been cancelled as requested in the amendment of Paper filed on May 17, 2004. Claims 1, 5, 6, 8, 9 and 16-18 are pending in the instant application.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael J. Sullivan on June 07, 2004.

The application has been amended as follows:

1. (Currently amended) A method for assessing risk of Alzheimer's Disease in a subject, which method comprises:

determining the [a] level of anti- β -amyloid-42 ($A\beta_{42}$) antibody in a biological sample selected from the group consisting of blood, serum, and plasma from a subject,

comparing the level of anti- $A\beta_{42}$ antibody in the biological sample from the subject to a normal level determined from an average of the level of anti- $A\beta_{42}$ antibody in a biological sample from a population consisting of age-matched normal subjects who do not show any symptoms of neurodegenerative disease or disorder associated with amyloidosis, wherein a statistically significantly lower level in the biological sample from the subject indicates the risk of Alzheimer's Disease.

16. (Currently amended) A method for assessing risk of Alzheimer's Disease in a subject, which method comprises:

determining the [a] level of anti- β -amyloid-42 ($A\beta_{42}$) antibody in a biological sample selected from the group consisting of blood, serum, and plasma from a subject, wherein the subject does not exhibit symptoms of cognitive dysfunction or memory dysfunction,

comparing the [a] level of anti- $A\beta_{42}$ antibody in the [a] biological sample[,] to a normal level determined from an average of the level of anti- $A\beta_{42}$ antibody in a biological sample from a population consisting of age-matched normal subjects who do not show any symptoms [of] associated with Alzheimer's Disease, wherein a statistically significantly lower level in the biological sample from the subject indicates the risk of Alzheimer's Disease.

3. It is noted that the extension of time is not necessary because Examiner's Amendment is required to resolve issues not previously of record.

4. Claims 1, 5, 6, 8, 9 and 16-18 are allowed. Claims 1, 5, 6, 8, 9 and 16-18 are renumbered as 1-8, respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.


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